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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,662	01/30/2001	Albert Zorko Abram	A33760PCTUSA	3549

20872 7590 11/01/2002

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/719,662	Applicant(s) ABRAM, ALBERT ZORKO	
	Examiner Clinton Ostrup	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *34* is/are allowed.

6)☒ Claim(s) *1-18 and 20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *19* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-18 and 20-34 are pending in this application.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 19-33 have been renumbered as claims 20-34, respectively, because claim 19 was cancelled in the amendment filed January 30, 2001 (Paper No. 5). The examiner respectfully request applicant provide a clean copy of all pending claims in response to this office action to cure any ambiguities as to what claims are pending in this application.

Response to Amendment

Claim Rejections - 35 USC § 112- New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 20-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 18 have been amended to add the limitation "the pharmaceutical agent being solubilized in the composition but insoluble in both water and the occlusive agent" and claim 20 has been amended to add the limitation "the pharmaceutical agent being solubilized in the composition but insoluble in both water and petrolatum. Although the specification, at page 2, lines 9-18, provides antecedent basis for the active ingredient being insoluble in both water and the occlusive agent, the specification does not appear to provide antecedent basis for the active ingredient being solubilized in the composition but not soluble in both water and the occlusive agent. Therefore, one skilled in the art would not expect an active ingredient that is insoluble in both hydrophobic and hydrophilic environments to be solubilized in the composition, particularly without a surfactant or emulsifier, as instantly claimed in claims 1, 18, and 20.

Response to Applicant's Arguments/Amendment

Applicant's arguments filed August 16, 2002, Paper No. 18, to the rejection of claims 1-10, 12-14, 16-18, 20-26, 28-30 and 32-33 under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and further in view of Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam have been fully considered but are not found persuasive. Therefore, the said rejection has been MAINTAINED for the reasons in Paper No. 14, mailed March 18, 2002 and those found below.

Applicant argues that Davis teaches a suspended active, not a solubilized active, as claimed instantly and that there is no teaching in Davis to solubilize the particular active ingredient. First, as discussed above, the active solubilized in the composition appears to be new matter. Second, the rejection is an obviousness-type rejection and the Woodford reference clearly teaches solubilizing the corticosteroid in alcohol, thus meeting the limitation of "the pharmaceutically active ingredient being solubilized in the composition." See: page 100, col. 1, first full paragraph.

Applicants then argue that Woodford et al., do not suggest a formulation comprising an occlusive agent in an amount claimed instantly. The examiner respectfully disagrees. The instant specification at page 4, first paragraph, teaches "the occlusive agent is present in an amount sufficient to permit the formation of an occlusive layer or hydration barrier on the skin of the patient...the amount of occlusive agent in the mousse composition may be up to approximately 55%," thus, because no lower limitation is specified by the specification, this amount includes zero percent. However, the Woodford reference clearly teaches 2.0 grams of a non-emulsifying wax being present in the formulation, therefore meeting the amounts of occlusive as claimed instantly.

Applicant then argue that the formulations of Woodford et al., have no occlusive properties that would suggest the claimed formulations or that occlusive properties in a foam would be achievable. Applicant agues that because Woodford uses a polyester film to provide occlusion on the skin when Woodford is assessing the efficacy and bioavailability of their compositions, that

Woodford indicates that the formulations themselves do not provide for occlusion. The examiner respectfully disagrees. There are numerous reasons for applying a polyester film to the skin, such as a method of controlling external influences on the skin. It appears that Woodford is applying a film to control external influences on the skin, thus being able to solely measure the efficacy and bioavailability of his composition.

Furthermore, page 103, col. 2, first full paragraph, Woodford et al., teach that "the precipitation of the wax from the solution produced a foam that collapsed on the skin as the wax re-dissolved at skin temperature." Thus, contrary to applicants assertion that formulations of Woodford do not have any occlusive properties that would suggest the claimed formulations, a wax which precipitates on the skin, in amounts taught by Woodford et al., suggest an occlusive agent in the amounts claimed instantly.

Applicant's arguments filed August 16, 2002, Paper No. 18, to the rejection of claims 1-14, 16-18, 20-30, and 32-33 under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam and further in view of Jones et al., have been fully considered but are not found persuasive. Therefore, the said rejection has been MAINTAINED for the reasons in Paper No. 14, mailed March 18, 2002 and those found below.

Applicant's argument that the Jones et al., does not cure the deficiencies of Davis and Woodford because Jones is relied upon for the particular emulsifier

in dependent claims 11 and 27 are not convincing because contrary to applicants assertion, the amendment to claims 1, 18, and 20 have not overcome the prior art rejection. Therefore, the rejection of claims 1-14, 16-18, 20-30, and 32-33 has been MAINTAINED for the reasons set forth in Paper No. 14.

Applicant's arguments filed August 16, 2002, Paper No. 18, to the rejection of claims 1-10, 12-18, 20-26, and 28-33 under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam and further in view of Gers-Barlag et al., have been fully considered but are not found persuasive. Therefore, the said rejection has been MAINTAINED.

Applicant's argument that the Gers-Barlag et al., does not cure the deficiencies of Davis and Woodford because Gers-Barlag is relied upon for the amounts of aqueous solvent and propellant of instant claims 13, 15, 17, and 31 are not convincing because contrary to applicants assertion, the amendment to claims 1, 18, and 20 have not overcome the prior art rejection. Therefore, the rejection of claims 1-14, 16-29, and 31-32 has been MAINTAINED for the reasons set forth in Paper No. 14.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, 12-14, 16-18, 20-26, 28-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and further in view of

Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam.

Davis teaches an antibiotic, water-soluble foam and a dispenser system for applying said foam. The reference teaches using white petrolatum, distilled water, alcohols and hydrocarbon propellant gas mixtures to deliver the active ingredient silver sulfadiazine. The reference teaches the use of fatty alcohols, emollients, emulsifiers, humectants, as well as the addition of other ingredients including steroid preparations.

Although the primary reference teaches an aerosol foam comprising the occlusive agent petrolatum, aqueous and organic solvents, propellants, and emulsifiers and surfactants, it lacks an active ingredient which is insoluble in both water and the occlusive agent.

Woodford et al., teach topically applied bioactive aerosol quick-break foams in aqueous-alcoholic systems comprising a non-ionic wax, moisturizers, and propellants. The reference teaches the specific corticosteroids, betamethasone valerate and clobetasol propionate as useful in the invention. The secondary reference teaches that the quick-break aerosol foam offers several advantages including ease of application, controlled dosage from a metered valve, economy in use, suitability for smooth or hairy skin and reduced inhalations as compared to other aerosol sprays.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical antibacterial foam of Davis, by adding corticosteroids as taught by Woodford et al., because of the expectation

of obtaining a quick-break aerosolized foam composition which could be used to deliver skin treatment compositions in a safe, economic way.

Claims 1-14, 16-18, 20-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717, Woodford et al., Bioavailability and Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam as applied to claims 1-10, 12-14, 16-18, 20-26, 28-30, and 32-33 above and further in view of Jones et al., **WO 96/27376.**

Although the combination of references above teach a topically applied quick-break bioactive foam as described above, they lack the specific emulsifier as claimed instantly in claims 11 and 27.

Jones et al., teach a quick-break foamable pharmaceutical composition comprising a corticosteroid, a quick-break foaming agent, a propellant and a buffering agent. The Jones reference teaches as an Example betamethasone valerate, water, alcohol, and the specific emulsifier of instant claims 11 and 27, Polysorbate 60 and teaches that polysorbate 60 is particularly prefer because it enhances the fatty alcohol solubility in the system and enhances foam formation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the quick-break foam composition of the combined references above by adding polysorbate 60 as taught by Jones et al., because of the expectation of obtaining a quick-break foam with an emulsifier that enhances the foam and the fatty alcohol solubility.

Claims 1-10, 12-18, 20-26, 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,143,717 and Woodford et al., Bioavailability and

Activity of Topical Corticosteroids for a Novel Drug Delivery System, the Aerosol Quick-Break Foam as applied to claims 1-10, 12-14, 16-18, 20-26, 28-30, and 32-33 above and further in view of Gers-Barlag et al. 5,833,960.

Although the combination of references above teach a topically applied quick-break bioactive foam as described above, they lack the cosolvent of instant claims 15 and 31.

Gers-Barlag et al. describe foaming, light protection preparations and a method of using them to protect skin from harmful wavelengths of light. See: abstract and col. 12, line 37- col. 13, line 11. Foams, according to the secondary reference, allow a fine distribution of substances onto the skin. See: col. 9, lines 3-28. The secondary reference describes the oil phase as comprising 1%-50% by weight of the preparation. See: col. 15, lines 24-27. The secondary reference describes mixtures of C_{12-15}–alkyl benzoates, the specific organic solvent of claim 15, and other compounds as particularly advantageous in the oil phase. See: col. 14, line 60 – col. 15 line 5.

The secondary reference teaches the use of aerosol container and an amount of 5.00% by weight of a propellant (butane/isobutane/propane). Thus, meeting the specific limitations of claim 17. See: col. 16, Example 3. Further, the reference teaches the addition of water to an aqueous phase to make the composition have a sum total of 100.00% by weight. The amount of water added to the formulation meets the specific limitations of claim 13. See: col. 15, line 28 - col. 16, line 68.

Gers-Barlag et al. further describe less soluble components in the formulation as having better spreadability than in formulations known in the art. See: col. 9, lines 9-14. The secondary reference describes the formulation as having "particularly good skin compatibility, making it possible to spread valuable ingredients particularly well on the skin." See: col. 9, lines 15-29.

It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the quick-break aerosol skin treatment foam compositions of the combined references by adding the amounts of aqueous solvent and propellant as well as the alkyl benzoates as taught by Gers-Barlag et al. because of the expectation of obtaining an aerosol foam skin treatment composition which provides good skin compatibility and makes it possible to spread valuable, less soluble ingredients particularly well on the skin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

October 29, 2002

PRIMARY EXAMINER